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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,297	10/30/2003	Lawrence W. Stark	39569-2661D	2549
7590	08/15/2005		EXAMINER	
Mikael Havlucian Heller Ehrman White & McAuliffe LLP 7th Floor 4350 La Jolla Village Drive San Diego, CA 92122-1246			MANUEL, GEORGE C	
			ART UNIT	PAPER NUMBER
			3762	
DATE MAILED: 08/15/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/699,297	STARK ET AL.
	Examiner George Manuel	Art Unit 3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-14 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 1-14 is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____.	6) <input type="checkbox"/> Other: ____.

## DETAILED ACTION

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 2 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 43, 47 and 49 of U.S. Patent No. 6,820,979. Although the conflicting claims are not identical, they are not patentably distinct from each other because one of ordinary skill in the art would have found it an obvious activation of the stimulus light source of claim 49 to control the amplitude of the light source because the pupil is sensitive to light fluctuations. Regarding claim 2, one of ordinary skill in the art would have found detecting neurological deterioration an obvious variation of comparing the first set of data and the second set of data such that neurological disease may diagnosed based on the comparison since deterioration is a type of disease.

Claims 1-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12 and 13 of U.S. Patent No. 6,116,736. Although the conflicting claims are not identical, they are not patentably distinct from each other because pupillary latency, constriction velocity, dilation velocity, amplitude, diameter, segmental dynamic and static analysis are obvious variations of pupil response to illumination as set forth in claim 12. Storing and controlling temporal data is an obvious adaptation for microprocessor control as claimed in claim 13. Synchronizing and amplitude modulating a light source are obvious microprocessor control features for programming brightness of a light source. Regarding claim 10, one of ordinary skill in the art would have found it obvious to convert the data for a pixel brightness threshold value to a scalar value because brightness lacks directional characteristics.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 7 and 9-14 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Dal Santo '109.

Regarding claims 1, 8, 9, 10, 13 and 14, Dal Santo discloses a microprocessor to control and drive the sequencing and operation of the optical pack 13 including the illumination source and the visible-light emitting diodes. The light source is amplitude modulated based on LEDs 36A and 36B such that, the control unit 11 will light LED 36A if the presence of drugs is detected, and LED 36B if drugs are not detected. The examiner is interpreting LEDs 36A and 36B to comprise scalar values when illuminated and to operate in both a static and dynamic modes.

Regarding claims 11 and 12, the internal control pack 11 generally includes an electronic data storage apparatus, for storage of instrument software, test input data, pupillary response data, and analytical results, such as, read-only permanent memory (ROM), random access memory (RAM) and/or disk-based storage such as floppy-disk or miniaturized hard-drive technology.

Regarding claim 7, Dal Santo teaches producing an electrical output signal that is indicative of the pupil diameter of eye 40 over a period of time based on the reflected illumination or IR light.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dal Santo '109.

Dal Santo shows all of the claimed features except for pupil latency, constriction velocity, dilation velocity, and pupillary amplitude. One of ordinary skill in the art would have found it an obvious modification of the teaching to produce an electrical output signal that is indicative of pupil diameter over time to provide indicia for pupil latency, constriction velocity, dilation velocity and pupillary amplitude because these are characteristics of the pupil that describe the diameter and change as a function of the diameter and time.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George Manuel whose telephone number is (571) 272-4952.



George Manuel  
Primary Examiner  
Art Unit: 3762

8/11/05